

THROMBOEMBOLIC EVENTS ASSOCIATED WITH LENALIDOMIDE

A REVIEW AFTER THE EMA ALERT

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Lenalidomide and incremented risk of arterial and venous thromboembolic events (AVTE)



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- Recommended administration of antithrombotic prophylaxis.
- Recommended avoidance of erythropoietic agents, specially when other risk factors (RF) are present.



OBJECTIVES

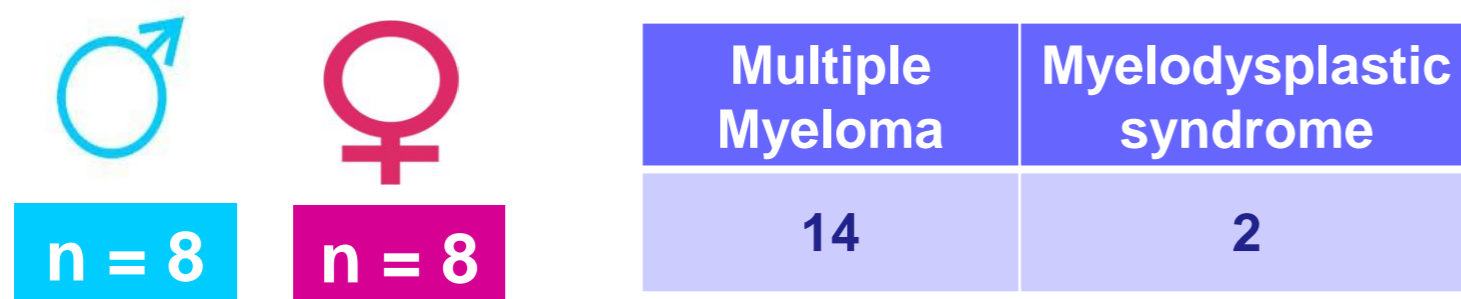
To analyze the incidence of AVTE and the presence of RF in patients treated with lenalidomide.
To assess treatments with lenalidomide in relation to EMA's warning.

MATERIAL AND METHOD

Observational retrospective study. Treatments with lenalidomide started in period: may 2008 – september 2010.

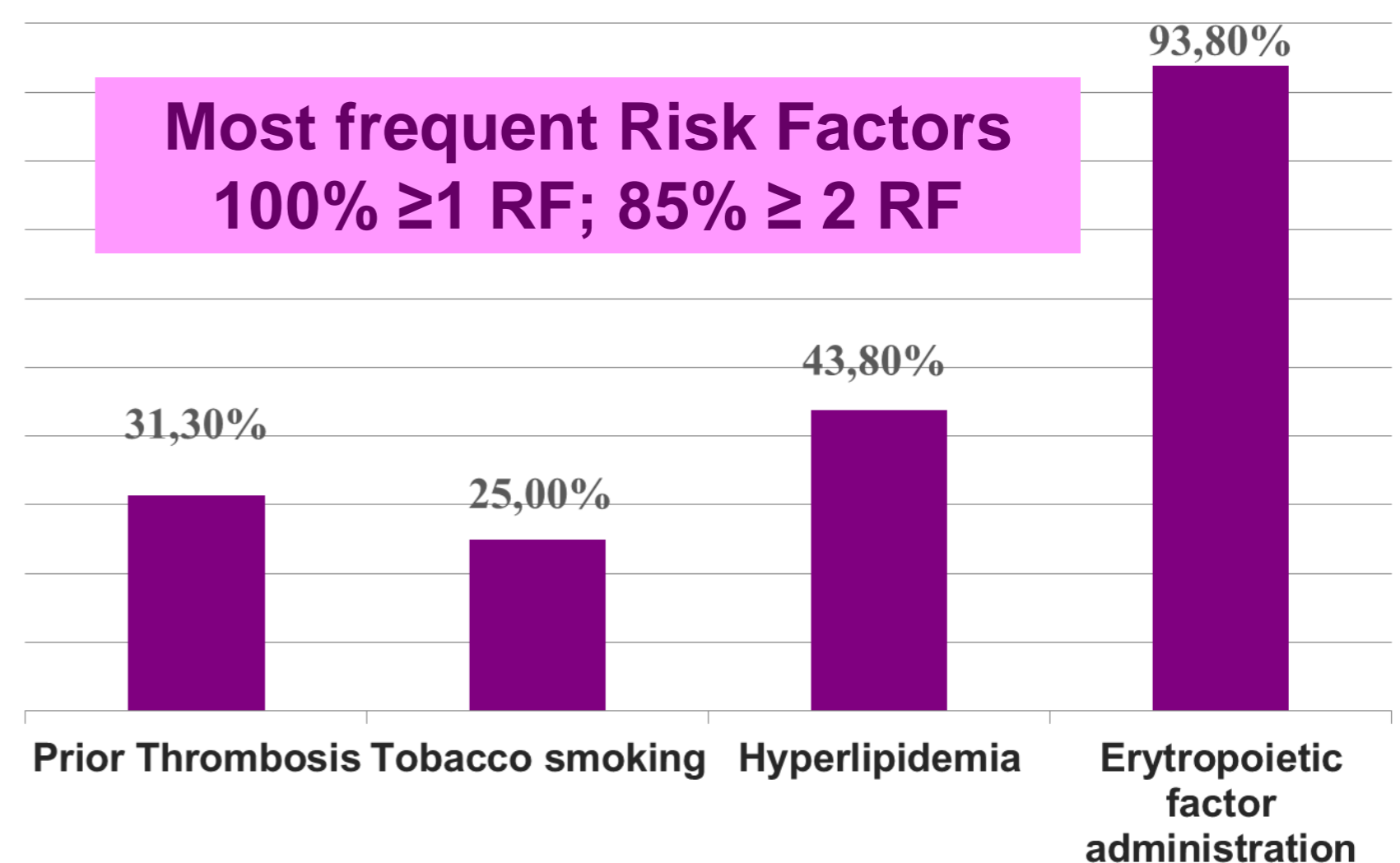
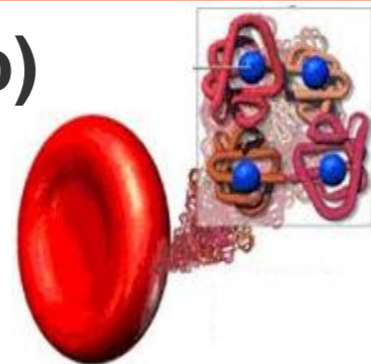
RESULTS

- Population: n= 16. Age 68.3 years (CI 95% 63.1-73.4)
- Average number of cycles per patient: 6 (range 2-21)



Maximum hemoglobin levels (Hb)

Median: 12,5 g/dl
Range: 9,1 – 14.1 g/dl



Antithrombotic prophylaxis (AP)

81,3% patients received low molecular weight heparins (LMWH) or oral anticoagulants

Arterial and venous thromboembolism Events (AVTE): 3 patients

| Erythropoietic factors | Cycle number | Previous AP | Hb > 13 g/dl | Lenalidomide Treatment |
|------------------------|--------------|-------------|--------------|------------------------|
| Continued after AVTE | 2 | NO | NO | Spaced out |
| Continued after AVTE | 3 | YES (LMWH) | NO | Stopped |
| Continued after AVTE | 7 | YES (LMWH) | NO | Continued |

CONCLUSIONS

All patients presented thromboembolism risk factors and most received antithrombotic prophylaxis.
No relation between risk factors and thromboembolic events was found.